In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-696V

(to be published)

ARLYNE ROTHENBERG,	*	Special Master Corcoran
Petitioner,	*	Filed: April 19, 2018
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Tetanus Diphtheria Acellular Pertussis ("Tdap"); Autoimmune Injury; Lipodystrophy; Onset; Preexisting Symptoms.
Respondent.	*	

John McHugh, New York, NY, for Petitioner,

Heather L. Pearlman, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION ON RECORD DENYING COMPENSATION[1]

On July 6, 2015, Arlyne Rothenberg filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petitioner claims that a variety of symptoms she suffered (including pain in her joints, bones, and muscles, plus abdominal cramping, neuropathies in her limbs, gastrointestinal distress, and microcytic anemia) were autoimmune in nature, and all caused by the Tetanus-diphtheria-acellular pertussis ("Tdap") vaccine she received on July 21, 2012. *See* Petition ("Pet.") at 1 (ECF No. 1).

[1] Because this Decision contains a reasoned explanation for my actions in this case, I will post it on the United States Court of Federal Claims website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

After submitting expert reports, the parties agreed to have the Petition decided on the papers instead of via a hearing. I have now had the opportunity to review all filings in the case and the parties' respective arguments, and I hereby DENY entitlement. As discussed in greater detail below, Petitioner's symptoms and alleged injury are more readily attributable to sequelae she experienced from gastric bypass surgery she underwent 20 years ago than to the Tdap vaccine. In addition, Petitioner's causation theory is unreliable and unpersuasive.

I. Factual Background

Vaccination and Subsequent Medical History

Petitioner, then 55 years old, received the Tdap vaccine on July 21, 2012, at Urgent Care Manhattan in New York City after stabbing her right hand with a box cutter a few days before. Ex. 12 at 4; Pet. at ¶2; *see also* Ex. 4 at 140; Ex. 10 at 3; Ex. 21 at 3. Her medical history at the time of vaccination was extensive and included anxiety disorder, depression, and neuropathic pain, as well as having undergone gastric bypass surgery in 1993. Ex. 3 at 4, Ex. 11-1 at 89. In addition, Ms. Rothenberg had suffered from osteomalacia[3] secondary to the gastric bypass, and had a history of bilateral hip pain. Ex. 3 at 10, Ex. 13 at 1. She also received treatment in the past for hypothyroidism, gluten sensitivity, colitis, anemia, Hashimoto's disease, chronic kidney disease, and hernia surgery. Ex. 1 at 6; Ex. 3 at 4, 10; Ex. 5 at 1; Ex. 8 at 2; Ex. 11 at 1; and Ex. 12 at 4.

The medical records set forth no initial complaints of an adverse reaction to the July 2012 vaccination. The next medical record chronologically is from August 27, 2012 (nearly five weeks post-vaccination), when Petitioner saw Dr. Ira Breit at Westside Medical Associates to treat "skin problems." Ex. 2 at 6-7. Ms. Rothenberg specifically complained of itchy skin, a problem she claimed to have experienced since her teen years, and also stated that she was suffering from bone and muscle pain. She requested that she receive some kind of hormone therapy treatment from Dr. Breit at this time, although he agreed only to perform a blood test. *Id.* at 6. After examination, Dr. Breit's impression was that Petitioner had alopecia and a rash, along with vitamin D and iron deficiencies of an unspecified etiology. *Id.* at 7. This record does not refer at all to the July Tdap vaccination.

On September 14, 2012, Ms. Rothenberg returned (after a two-year interval) to the Osteoporosis Center at the NYU Hospitals Center in New York City, complaining of severe pain

[3] Osteomalacia is the adult equivalent of the childhood disease rickets, and is characterized by "inadequate or delayed mineralization" of bone matrix in cortical or spongy bone. *Dorland's Illustrated Medical Dictionary* 1346 (32nd ed. 2012) (hereinafter "*Dorland's*"). Like rickets, it can be caused by vitamin D or calcium deficiencies, whether attributable to diet or underlying malabsorption abnormalities. *Dorland's* at 1644.

in her joints and muscles "over the past few months" (a timeframe that could extend to, or beyond, the date of her Tdap vaccination). Ex. 3 at 1. She saw Dr. Stephen Honig, a rheumatologist with a special interest in osteoporosis. She also complained of burning skin, and related the view that her vitamin D deficiency (which she had found difficult to treat) interfered with her ability to remedy her bone pain. *Id*. On examination, the only noted abnormality was a mild ridging of Petitioner's first carpal metacarpal joint on the left wrist. *Id*. Dr. Honig prescribed medication to increase Petitioner's calcium levels, and considered injections of vitamin D as well. Like the August record, however, this medical record does not refer to the July Tdap vaccination, and Dr. Honig's assessment only included conditions that Ms. Rothenberg was already known to have, like osteomalacia. *Id.*

The following month, Petitioner returned to Dr. Honig several times. Ex. 3 at 1-4. On October 12, 2012, she reported that her pain had lessened after using a sun lamp to increase her vitamin D levels, although she was still experiencing bone and muscle pain. *Id.* at 1-2. Her diagnosis remained the same from her September visit, however, and Dr. Honig characterized her as "in no acute distress." *Id.* at 2. On October 15, 2012, Dr. Honig reviewed the results of the blood testing he had previously ordered, observing an improvement in her vitamin D level, but also noting that she remained anemic, and displayed a high erythrocyte sedimentation rate ("ESR"),[4] which can reflect ongoing inflammation. Based upon the foregoing, Dr. Honig proposed that "there may be another reason for her diffuse pain" beyond her osteomalacia. *Id.* at 4.

Then, on October 17, 2012 (now nearly three months post-vaccination), Ms. Rothenberg returned to the NYU Hospitals Center, complaining of bone and muscle pain similar to what she had previously reported, and was seen by Dr. Tibor Moskovits, a hematologist. Ex. 3 at 4-6. Although Dr. Moskovits observed Ms. Rothenberg to be in "mild distress," she was deemed normal after examination. *Id.* at 6. Dr. Moskovits proposed that her persistent anemia was attributable to an iron deficiency, and offered several possible treatments for it. He also speculated that the observed ESR increase could be the result of a decreased hemoglobin level. *Id.* at 6.

A week later, Petitioner returned to Dr. Honig at the Osteoporosis Center on October 24, 2012. Ex. 3 at 6-10. She complained of pain consistent with her prior reports, but added that she now also felt aching in her legs. At this visit, Petitioner specifically mentioned the incident from July that resulted in her receipt of the Tdap vaccine, and voiced her belief that her symptoms had since that time "exploded." *Id.* Dr. Honig offered no additional views as to the proper diagnosis

[4] Erythrocyte Sedimentation Rate or "ESR" is a blood test used to show inflammatory activity in the body. *Sed Rate (Erythrocyte Sedimentation Rate)*, Mayo Clinic, https://www.mayoclinic.org/tests-procedures/sed-rate/about/pac-20384797 (last accessed Apr. 4, 2018). It measures the distance red blood cells fall in a test tube in one hour. *Id.* The further the cells descend in the tube, the greater evidence of an inflammatory response of the immune system. *Id.*

for her symptoms or their etiology, however – nor did he state that he concurred with Petitioner's suspicions as to a potential relationship between her Tdap vaccination and her ongoing symptoms.

Efforts to Identify Alternative Causes for Petitioner's Pain

Later in the fall of 2012, Petitioner saw other kinds of specialists in a quest to identify the cause of her symptoms. On November 5, 2012, Ms. Rothenberg was evaluated by Dr. Michael Holick, an endocrinologist at Boston Medical Center in Massachusetts. Ex.13 at 1-3. The record from this visit reveals that Ms. Rothenberg had been "in touch" with Dr. Holick since 2005, "complaining of osteomalacia symptoms" which she associated (consistent with prior records) with her gastric bypass surgery. *Id*. The record's notations are consistent with those from October 2012 (e.g. an ongoing vitamin D deficiency, complaints of aches and pains, etc.), but Petitioner did not mention her Tdap vaccination. Dr. Holick noted that Petitioner was "healthy-appearing," but ordered additional tests to see if some explanation for her pain and related symptoms could be obtained. *Id.* at 2.

Next, in mid-November, Ms. Rothenberg saw another endocrinologist, Dr. Robert Lind of the NYU Hospital Center, based on Dr. Honig's prior referral. Ex. 3 at 10-11. Dr. Lind understood the reason for the visit was to evaluate and treat Petitioner's long-existing vitamin D deficiency plus "hyperparathyroidism," although Petitioner did inform Dr. Lind that she believed her bone and muscle pain had worsened after the July vaccination. *Id.* at 10. She informed Dr. Lind of her recent visit to Dr. Holick, and that he had speculated that she might have Ehlers-Danlos syndrome.[5] *Id.* at 11. Dr. Lind was unable to propose an explanation for Ms. Rothenberg's symptoms other than her "underlying osteomalacia," but suggested additional testing, including a bone and skeletal survey. *Id.* at 13. X-rays of Petitioner's hands and feet performed later that month were consistent only with osteomalacia, however, as was the skeletal survey, although the bone scan that had been ordered could not be completed. *Id.* at 14-21.

2013 Hospitalizations

The next records most directly relevant to Petitioner's claim are from February 2013 – now over six months from the date of vaccination.[6] On February 1, 2013, Ms. Rothenberg was admitted

[5] Ehlers-Danlos syndrome is an umbrella term describing a group of connective tissue disorders and characterized by hyperextensible joints, bruisability, and poor wound healing, among other things. *Dorland's* at 1828.

[6] In the late evening of December 26, 2012, Ms. Rothenberg went to the emergency department of New York Presbyterian-Weill Cornell Hospital, primarily complaining of a "funny feeling on face." Ex. 4 at 2. In the process, she also complained of muscle dysfunction over the prior 10 days, but did not mention any of the bone or muscle pain symptoms previously described herein. *Id.* at 4. Her vital sign measurements were normal, however, and the record from this emergency visit sets forth no diagnosis or assessment of the cause of her complained symptoms. *Id.* at 5-6.

to Mount Sinai Hospital in New York from its emergency department after complaining of a number of symptoms. *See generally* Ex. 11-1 at 30-34. In particular, she reported experiencing painful diarrhea that had been ongoing for two weeks, but added as well her belief that her "problems" had begun six months before, after her Tdap vaccine had triggered a "neuropathy" in her arms and stomach (although she also admitted that she had repeatedly experienced similar symptoms once or twice a year since the gastric bypass operation, and that the symptoms typically resolved on their own). *Id.* at 30, 38.

Ms. Rothenberg obtained an initial evaluation from a gastroenterologist, Dr. Peter Chang. Ex. 5 at 1-14. Her vital signs were deemed normal and stable over the time of her admission, and her oxygen saturations were normal, as was the physical examination. Ex. 11-1 at 40-41. The initial differential diagnosis focused on a variety of possible gastroenterologic illnesses and disorders, and a wide variety of tests were proposed, including performance of a colonoscopy, stool studies, endoscopic evaluations of the upper gastrointestinal system, and gut tissue biopsies. *Id.* at 42. Besides Dr. Chang, Petitioner also received treatment from a hematologist, Dr. Robert Krafter, who evaluated her anemia and recommended that it could be treated if Petitioner more strictly followed the proper diet for a person who had previously received gastric bypass surgery. *Id.* at 43, 48.

Ms. Rothenberg was discharged from Mt. Sinai on February 12, 2013. Ex. 11-1 at 27-28. On discharge, she was diagnosed as having "intestinal malabsorption," the treatment of which would require follow-up testing. *Id.* at 28. But the anemia, diarrhea, and vitamin deficiencies she displayed after hospital testing were all deemed to have been successfully treated. *Id.* A few weeks after, Dr. Chang prepared a handwritten summary of his treatment and assessment of Petitioner after seeing her for a follow-up visit. Ex. 5 at 15. That note stated that the esophago-duodenal (EGD) biopsy that was performed on Petitioner was negative. *Id*. Dr. Chang also allowed for the possibility that all of Petitioner's symptoms were ultimately related to nutritional deficiency, but proposed that he see Ms. Rothenberg again in a few weeks to evaluate her overall recovery. *Id.*

On March 8, 2013, Ms. Rothenberg was admitted a second time to Mt. Sinai after returning to its emergency room, now complaining of shortness of breath and headache, along with acute chest and left arm pain. Ex. 11-4 at 328, 330. The pain had begun after Ms. Rothenberg had ceased receiving intravenous feeding from a catheter line inserted after her last hospitalization, and there was an initial concern that the site of the line's insertion might be infected. *Id.* at 330; Ex. 11-6 at 595. The attending ER physician recommended that Petitioner be admitted as an inpatient because she appeared "chronically ill" and malnourished, and felt there was a risk of "short term decompensation" if she were not admitted. Ex. 11-4 at 328.

Petitioner remained at Mt. Sinai until March 21, 2013. Ex. 11-4 at 335-38. Eventually her treaters determined that she had experienced a thrombus in the left subclavian vein associated with the point of insertion of the intravenous feeding line, and also likely did have a related infection. *Id.* at 338; Ex. 11-6 at 532. Test results were otherwise normal. *Id*. at 596-605. Her discharge summary included no reference to her other prior conditions, like osteomalacia, as having any connection to the hospitalization, nor did it mention her July 2012 vaccination.

Subsequent Treatments and Record References to Lipodystrophy

Over the next nine months, Petitioner's health remained mostly stable - although it was not especially robust, as the same kinds of problems that led her to seek treatment before continued to plague her. In the spring and summer of 2013, Ms. Rothenberg sought additional treatment for her anemia and concurrent iron deficiency. *See, e.g.*, Ex. 6 at 1, 4, and 6-8. She also obtained medical assistance with her feeding catheter. Ex. 11-8 at 715; Ex. 5 at 15-16. She had an additional overnight hospitalization on October 21-22, 2013, due to complaints of chest pain, palpitations and shortness of breath. Ex. 11-9 at 756, 770. The main assessment from that short admission was gastric malabsorption attributable to her dependence on intravenous feeding. *Id.* at 786, 789.

Petitioner's primary identified vaccine injury is lipodystrophy, or defective fat metabolism that can result in the absence of subcutaneous fat.[7] Record references to this disorder exist – but they are spotty at best, and do not suggest that Ms. Rothenberg was in fact ever formally so diagnosed. For example, Petitioner went to Dr. Joseph Jorizzo, a dermatologist, in October 2013 complaining of a growth on her face that she feared was related to scleroderma (attributable in turn to the same kind of malabsorption issues she had experienced in the past). Ex. 14 at 1. Dr. Jorizzo did not confirm her suspicions, however, and after examination largely counseled her to protect her skin in commonly-understood ways, such as through the use of sunblock. *Id.* at 4.[8]

Ms. Rothenberg also returned to Dr. Chang again in October 2013, reporting concerns of "abdominal distending" that had occurred "overnight." Ex. 5 at 16. Dr. Chang observed a "significant excess of skin and adipose tissue above [the] abdominal musculature," but maintained that "the problem" was attributable merely to a lack of exercise and resulting muscle loss, adding that it was unlikely the change had occurred as quickly as Petitioner maintained. *Id.*

[7] *Dorland's* at 1062.

[8] In May 2015, Ms. Rothenberg consulted Dr. Harry Spiera, a rheumatologist, who stated unequivocally: "I do not find any evidence of scleroderma [petitioner expressed concern that she had it] or any other autoimmune disease." Ex. 8 at 2. In so doing, he referenced Petitioner's self-reported history of experiencing dramatic health changes after receipt of the Tdap vaccine. *Id.* at 1.

Ms. Rothenberg saw Dr. Jorizzo again in December 2013 – now representing that she was experiencing "skin thinning" all over her body. Ex. 14 at 5. She also reported to Dr. Jorizzo that her condition had been "diagnosed to be acquired lipodystrophy" – although the medical record contains *no* such diagnosis prior to this time. *Id.* Dr. Jorizzo examined Ms. Rothenberg again, and although the "encounter diagnoses" include the phrase "partial lipodystrophy," it does not appear from *this record* that Dr. Jorizzo was embracing this as a reasonable potential diagnosis. *Id.* at 7. Indeed – consistent with his examination two months before, Dr. Jorizzo largely seems to have concluded that Petitioner had no identifiable skin problems, and spent some time explaining this to her. *See, e.g., id.* at 7 ("rediscuss why not scleroderma").

From this point on, there are large temporal gaps in the medical record before Petitioner's alleged injuries are again referenced. Petitioner returned to Dr. Jorizzo six months later, on June 28, 2014, at which time she complained that her skin condition remained "unstable," but after examination Dr. Jorizzo identified "no objective derm findings." Ex. 14 at 9, 11. Although he included lipodystrophy in the encounter diagnoses section of his write-up, he recorded his view that "the subcutaneous manifestations the patient describes are . . . from delayed metabolic issues from bariatric surgery." *Id.* at 11. No mention of lipodystrophy as an ongoing issue or concern is included in the record from Petitioner's September 2014 visit with Dr. Jorizzo. *Id.* at 13-15.

In September 2014, Petitioner returned to Westside Medical Associates and saw Dr. Stephanie Rein, an internist (whom Petitioner had also seen earlier that year as well). Ex. 2 at 83-84. A "progress note" from this visit references "lipodystrophy - loss of connective tissue. Triggered by tetanus shot??" *Id.* at 83. But the reference is not explained, and this record overall suggests Petitioner's primary reason for seeking medical help on this occasion was for treatment of insomnia. *Id.* at 84. The diagnoses from this visit with Dr. Rein do not include lipodystrophy. *Id.*

In mid-December 2014, Ms. Rothenberg went to Dr. Zvi Osterweil - an ear, nose, and throat ("ENT") specialist – for evaluation of possible obstructive sleep apnea. Ex. 7 at 1. The notes from this visit include lipodystrophy in Petitioner's medical history, and also mention it as a feature of her current health. *Id.* at 2. It does not appear, however, that Dr. Osterweil so diagnosed Petitioner. Five months later, in May 2015, Petitioner consulted with Dr. Eric Smouha, another ENT at Mount Sinai Hospital. Ex. 9 at 1. Dr. Smouha stated that the consult was for "problems with both ears secondary to lipodystrophy," and that Petitioner was there because she "was diagnosed with lipodystrophy 3 years ago after a DPT shot." *Id.* If temporally accurate, this would mean that Petitioner received the diagnosis in May 2012 – before the vaccination – although as noted above there is no such diagnosis found anywhere in the medical records from 2012 filed in this case. Dr. Smouha deemed the reports of ear shrinking "subjective," although (apparently

accepting as true Petitioner's reported lipodystrophy diagnosis) he allowed for the possibility that some of her condition could be reflective of lipodystrophy. *Id.* at 2.

II. Expert Reports

A. *Dr. Yehuda Shoenfeld*

Dr. Shoenfeld prepared two reports filed on Petitioner's behalf in this case. Report, dated December 1, 2016, filed as Ex. 20 (ECF No. 42) ("First Shoenfeld Rep."); Report, dated April 24, 2017, filed as Ex. 22 (ECF No. 48-1) ("Second Shoenfeld Rep."). Dr. Shoenfeld identifies himself as the current head of the Center for Autoimmune Diseases, which he founded at the Sheba Medical Center in Israel. Shoenfeld CV, dated Dec. 1, 2016, filed as Ex. 21 (ECF No. 42). He is also the Laura Schwarz-Kipp Chair for Research of Autoimmune Diseases at Tel Aviv University. *Id.* His experience focuses on autoimmune and rheumatic diseases, and he has published many peer-reviewed papers in journals and books on these topics. *Id.* He is on the editorial board of 32 journals in the field of autoimmunity. *Id.* Dr. Shoenfeld's background does not reveal expertise with the particular disease or illness claimed as the injury in this case.

Dr. Shoenfeld's first report began with a five-page summary of Ms. Rothenberg's medical history largely consistent with what is set forth above. First Shoenfeld Rep. at 6-11. He characterized lipodystrophy as "generalized or partial fat loss," adding that it can partially affect one half of a person's body. *Id.* at 11. Although he allowed for the fact that the etiology of lipodystrophy was generally unknown, he proposed that "signs of auto-immunity" had been identified in certain patients. *Id.* Specifically, cases of partial lipodystrophy have been associated with "complement abnormalities"[9] as manifested by the presence of a particular autoantibody. *Id.* In addition, case reports also demonstrated that individuals experiencing a variety of known autoimmune illnesses (lupus mainly, but also myasthenia gravis, immune thrombocytopenic purpura, scleroderma, and Hashimoto's thyroiditis) experienced lipodystrophy as well, suggesting it too is autoimmune in derivation. Dr. Shoenfeld added that Petitioner herself had suffered from a thyroid disease likely autoimmune, thereby rendering her susceptible to other autoimmune illnesses. *Id.* at 14.

Dr. Shoenfeld next discussed the link between vaccination and lipodystrophy. Lipodystrophy can be a "local adverse reaction" to corticosteroid injections, or the result of

[9] The complement system is a component of the innate immune system, and is comprised of various blood serum proteins that assist antibodies and phagocytic cells in clearing microbes and damaged cells from an organism, promote inflammation, and attack pathogens. *See, e.g.*, P. Sissons, et al., *The Complement Abnormalities of Lipodystrophy*, 294 New Eng. J. Med. 461-65 (1976), filed as Ex. 20-04 (ECF No. 42). Antibodies generated by the adaptive immune system can help cause the activation of the complement system.

"inappropriate" (meaning improperly administered) intramuscular injections. First Shoenfeld Rep. at 12. Vaccine-induced lipodystrophy is rare, but has been associated with the measles or human papillomavirus vaccines. *Id.* He also noted a single case report in which a woman experienced delayed lipodystrophy five months after receipt of the influenza ("flu") vaccine, plus case reports in which individuals receiving the HPV vaccine experienced localized lipodystrophy after the HPV vaccine. *Id.* at 13; *see* E. Javelle, et al., *Delayed Focal Lipoatrophy After AS03-Adjuvanted Influenza A (H1N1) 2009 Vaccine*, 29 Vaccine 1123 (2011), filed as Ex. 20-20 (ECF No. 42) (case report detailing single female patient who developed a small skin depression five months following flu vaccination); S. Ojaimi, et al., *Quadrivalent Human Papillomavirus Recombinant Vaccine Associated Lipoatrophy*, 27 Vaccine 48676 (2009), filed as Ex. 25-1 (ECF No. 54-1) ("Ojaimi") (case report discussing two female patients from Australia who developed skin depressions at the site of a HPV vaccine dose, which then worsened following subsequent doses); F. Stephan, et al., *A Case of Lipoatrophy Following Quadrivalent Human Papillomavirus Vaccine Administration*, 70 J. Am. Acad. Dermatology E132 (2014), filed as Ex. 20-22 (ECF No. 42).

A connection to the Tdap vaccine and lipodystrophy, by contrast, was only documented in passing by any of the literature reviewed by Dr. Shoenfeld. First Shoenfeld Rep. at 12. But Dr. Shoenfeld noted that reports of adverse effects after the Tdap vaccine were not rare. He also cited an observational study in which eight infants experienced injection site lipoatrophy[10] after receiving a DPT vaccination. *Id.* at 12-13; *see* K. Sardana, et al., *DPT Vaccine-Induced Lipoatrophy: An Observational Study*, 46 Int'l J. Dermatology 1050 (2007), filed as Ex. 20-19 (ECF No. 42) (retrospective case report review of all patients presenting with lipoatrophy following DPT administration between 2000 and 2005 in three hospitals in New Delhi, India). The study concluded, however, that the exact cause of lipoatrophy in these eight infants "was difficult to ascertain[,]" although the vaccine was considered a "possible factor." *Id.* at 1053. According to Dr. Shoenfeld, the local reactions were likely attributable to the antigens contained in the vaccine – and in particular use of whole cell pertussis or tetanus toxoid. First Shoenfeld Rep. at 14.

Dr. Shoenfeld went on to propose biological mechanisms by which the Tdap vaccine could produce lipodystrophy. In particular, he cited the vaccine's adjuvant, aluminum. First Shoenfeld Rep. at 14-15. He noted that aluminum has been shown to have toxic effects on the human body with respect to many different physiologic systems, and that it has been identified as the "culprit" in adverse reactions to vaccination. *Id.* at 14. "Direct aluminum toxicity" had, he maintained, been proposed as the actual mechanism for lipoatrophy after receipt of the HPV vaccine, pointing out that what looked to be aluminum residues could be seen at the site of injury. *Id.* at 15.

[10] Lipoatrophy is defined as "atrophy of subcutaneous fat." *Dorland's* at 1062.

Dr. Shoenfeld's second report was a two-page letter largely aimed at addressing points included in the first report of Respondent's expert, Dr. Levinson. In it, he made a number of points about Petitioner's purported lipodystrophy. First, he maintained that the diagnosis had been "confirmed" by several physicians (in particular referencing the trustworthiness of Dr. Jorizzo's comments – which, as noted above, report claims of a *prior* diagnosis of lipodystrophy but do not make one – because of his dermatologic expertise). Second Shoenfeld Rep. at 1. Second, he emphasized that Petitioner did not have lipodystrophy pre-vaccination, and that the disease in his view was progressive, with a long incubation period, thus explaining Ms. Rothenberg's overall course and the length of time it took for her symptoms to manifest. *Id.* Dr. Shoenfeld also contended that the autoimmune nature of lipodystrophy could not be credibly rebutted. *Id*. at 2. And he otherwise more clearly proposed an onset for Petitioner's symptoms – October 12, 2012 (almost three months after vaccination), when she saw Dr. Honig about her bone pain and ongoing vitamin D deficiency – and deemed it medically acceptable, although he did not elaborate as to why this was the case. *Id.* at 1.[11]

B. *Dr. Arnold Levinson*

Respondent offered two reports from Dr. Levinson. Report, dated April 3, 2017, filed as Ex. A (ECF No. 44-1) ("First Levinson Rep."); Report, dated July 31, 2017, filed as Ex. C (ECF No. 49-4) ("Second Levinson Rep.").

Dr. Levinson is currently an Emeritus Professor of Medicine and Neurology at the Perelman School of Medicine at the University of Pennsylvania. *See* Curriculum Vitae, filed as Ex. B (ECF No. 49-3) ("Levinson CV"); First Levinson Rep. at 1. During his career with the Perelman School, Dr. Levinson previously held the following positions: Chief of the Allergy and Immunology Section, Director of the Fellowship Training Program in Allergy and Immunology, and Director of the Center for Clinical Immunology. Levinson CV at 2. He received his undergraduate degree and medical degrees from the University of Maryland. *Id.* at 1. He is also currently board certified in internal medicine and allergy and clinical immunology. *Id.* at 2.

Over the course of his career, Dr. Levinson also conducted a clinical practice where he evaluated and treated patients with immune-mediated diseases, including autoimmune, hypersensitivity, and immunodeficiency disorders. First Levinson Rep. at 1. He has served on the editorial board of multiple journals, including the *Journal of Allergy and Clinical Immunology*. Levinson CV at 4. He has also published articles centering on immune-mediated diseases. *Id.* at

[11] Respondent also correctly notes that Dr. Shoenfeld's second report mistakenly concludes with reference to the HPV vaccine as causal (Second Shoenfeld Rep. at 2) – although because the report begins with mention of the Tdap vaccine, I interpret this as merely a typographical error.

6-21. Dr. Levinson considers himself an expert in the field of allergic and immunologic diseases. First Levinson Rep. at 1.

Like Dr. Shoenfeld, Dr. Levinson began his opinion with an overview of the relevant medical records. First Levinson Rep. at 2-6. But he also provided a more detailed discussion of lipodystrophy and its clinical characteristics. *Id.* at 7-8. As Dr. Levinson explained, there are several kinds of lipodystrophy, but all are "characterized by decreased body fat," distributed generally or only in one area of the body (in which case it is deemed "partial"). *Id.* at 7. Because Petitioner alleged that her lipodystrophy was vaccine-caused, Dr. Levinson focused on "acquired lipodystrophy," rather than congenital versions of the condition. *Id.*

A generalized form of acquired lipodystrophy is "Lawrence syndrome," which, though rare, can occur after an acute viral infection and is thought potentially to be autoimmune-associated. First Levinson Rep. at 7; *see* J. Capeau et al., *Human Lipodystrophies: Genetic and Acquired Diseases of Adipose Tissue*, 19 Endocrine Dev. 1, 12 (2010), filed as Ex. 20-1 (ECF No. 42) ("Capeau"). But it has a number of common comorbidities, including insulin resistance, cholesterol concentrations, and diabetes, among others. *Id.*; Capeau at 15. It also usually manifests within days or weeks of its instigation. First Levinson Rep. at 7. For an example of partial acquired lipodystrophy, Dr. Levinson referenced Barraquer-Simmons syndrome, which usually presents with outer-layer, subcutaneous fat loss in the upper body, although intramuscular and fat deposits within the body remain normal. Capeau at 13. As with generalized acquired lipodystrophy, a potential autoimmune association has been observed. First Levinson Rep. at 8.

Based on his review of the records. Dr. Levinson opined that Ms. Rothenberg had never experienced partial lipodystrophy. First Levinson Rep. at 9. He observed that he could find no evidence that any treater had actually so diagnosed her; rather, the records revealed that *she* informed treaters this was the case. *Id.* at 10. The very first reference to anything close to lipodystrophy, Petitioner's visit with Dr. Chang in October 2013, involved her claims of loss of muscle tissue, not fat, and did not include reported loss of fat in her upper body. *Id.* at 9. Thereafter, when Petitioner began to complain of skin problems or concerns about scleroderma, no evidence of abnormal fat distribution was observed, and some treaters disputed the accuracy of a lipodystrophy diagnosis to explain her symptoms, especially given the sequelae she had been experiencing for many years in the wake of her gastric bypass surgery. *Id.* at 10-11, 13.

Dr. Levinson also disputed Dr. Shoenfeld's assertions that lipodystrophy could be vaccine-caused. *See generally* First Levinson Rep. at 11-13. He noted there was a general lack of epidemiologic evidence supporting a connection. *Id.* at 11. To the extent case reports discussed in studies were the basis for such a link, he observed that most involved instances specific to the site of vaccine administration, rather than involving "adipose tissue site distant to the injection site."

Id. at 11-12. For example, Dr. Levinson cited to the Dahl and Morgan studies (also relied on by Dr. Shoenfeld in support of his theory). *See* P. Dahl, et al., *Localized Involuntary Lipoatrophy: A Clinicopathologic Study of 16 Patients*, 35 J. Am. Acad. Dermatology 523 (1996), filed as Ex. 20-12 (ECF No. 40); A. Morgan, et al., *Localized Reactions to Injected Therapeutic Materials*, 22 J. Cutaneous Pathology 289 (1995), filed as Ex. 20-13 (ECF No. 42). Neither of these studies, however, involved vaccine-caused "lipodystrophy at sites remote from the site of injection, *a point duly noted by the authors.*" First Levinson Rep. at 12 (emphasis added).

Dr. Levinson otherwise maintained that cases that seemed to suggest a relationship between vaccines (as opposed to other kinds of injections, like corticosteroids) and lipodystrophy were extremely rare, or otherwise distinguishable. First Levinson Rep. at 12. According to Dr. Levinson, the case reports by Dr. Shoenfeld (involving the HPV, H1N1 flu, and DPT vaccines), all seemed to exemplify the localized nature of any lipodystrophy observed. *Id.*[12] Of equal significance was the post-vaccination onset. Dr. Levinson noted that the "localized subcutaneous atrophic changes" that the case studies in question reported occurred "days to months" after injection. *Id.* The records in this case, by contrast, *at best* supported an onset of symptoms of lipodystrophy no sooner than approximately eighteen months after vaccination, in December 2013 – far too remote in time, even if the case reports were embraced as supportive of causation. *Id.*

Dr. Levinson's second report responded to Dr. Shoenfeld's April 2017 report. *See generally* Second Levinson Rep. He took direct issue with Dr. Shoenfeld's suggestion that the medical record evidenced significant loss of fat in Ms. Rothenberg's face sufficient to be deemed lipodystrophy, noting that this assertion had no support in the records, and that in fact the dermatologist who evaluated her, Dr. Jorizzo, had made "no findings" suggestive of lipodystrophy – rather, he proposed that "nutritional deficiencies" were the actual cause of any disparities in her lower body subcutaneous fat. *Id.* at 1-2. Dr. Levinson thus disputed Dr. Shoenfeld's contention that the record established *any* lipodystrophy diagnosis, let alone a valid one. Otherwise, Dr. Levinson reiterated his prior points about the limited value of the specific findings of the case studies cited, and the fact that Petitioner's well-documented preexisting health problems were all more likely explanations for her medical complaints than vaccine-caused lipodystrophy. *Id.* at 2-3.

[12] To the extent aluminum contained in the vaccines had anything to do with the adverse reaction, as Dr. Shoenfeld maintained, case studies offered to support this contention only underscored the fact that the lipodystrophy was a localized reaction to the site of vaccine administration, since it was in the "surrounding fat" where either traces of aluminum were observed, or where it would be expected that a reaction to the adjuvant would occur. First Levinson Rep. at 12; *see* Ojaimi at 4877 (stating that "aluminum has been suspected to play a role in the development of local reactions with other vaccines, such as DPT"); Stephan at E133 (noting that aluminum adjuvant is known to cause aluminum granuloma).

III. Procedural History and Ruling on Record Arguments

As noted above, the Petition was filed in July 2015. Thereafter, Ms. Rothenberg began gathering and filing relevant medical records, although the process had not been completed by the end of 2015. I eventually asked Respondent to prepare his Rule 4(c) Report based upon the available record, and he did so in April 2016, asserting that the case was not appropriate for compensation because, among other things, it required expert support to establish a sufficiently reliable causation theory. *See generally* Respondent's Rule 4(c) Report, dated April 12, 2016 (ECF No. 23) In particular, Respondent addressed the relevant facts of Ms. Rothenberg's health history and its likely relationship to her complaints. Report at 3-4.

The parties participated in a status conference in May 2016, at which time I set July 29, 2016, as the deadline for filing an expert report. Petitioner asked me to extend that deadline to the end of September (ECF No. 25), and I did so. That deadline, however, was delayed further, after Petitioner's first counsel withdrew from the case in the fall of 2016. But eventually, Petitioner filed Dr. Shoenfeld's first expert report in December 2016.

Several months passed before Respondent filed Dr. Levinson's first report in April 2017. Both sides also filed follow-up supplemental reports from each expert. Thereafter, I proposed to the parties that the matter be resolved on the papers rather than in a hearing, and they accepted my proposal. To that end, Petitioner filed her brief in support of her claim on September 23, 2017 (ECF No. 53) ("Mot."), and Respondent filed a memorandum arguing for dismissal of the matter on November 30, 2017 (ECF No. 57) ("Opp.").

Petitioner's brief included an overview of her medical history before turning to the elements of a successful Vaccine Act claim as set forth by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274 (Fed. Cir. 2005). She maintained that the initial, "can cause" element was met, asserting that there is "universal acceptance" of the association between the Tdap vaccine and lipodystrophy. Mot. at 8. Although she emphasized the case studies reporting localized associations, she noted that there was also support for "systemic" adverse effects, and that the aluminum adjuvant was suspected to be a source of such effects. *Id.* at 9, *citing* Ex. 20-18 (1981 article cataloging local and systemic reactions occurring within 48 hours in recently vaccinated DTP pediatric patients between 1978-1979), 20-19 (retrospective case report review of all patients presenting with lipoatrophy following DPT administration between 2000 and 2005 at three hospitals in New Delhi, India), 20-22 (2014 case report detailing a case of lipoatrophy following the HPV vaccine). She also reiterated Dr. Shoenfeld's point that a person like Petitioner with a known autoimmune condition (her preexisting thyroid problem) was more likely to have other autoimmune diseases. *Id.* at 9-10.

Regarding the second prong, Petitioner made additional first prong arguments, referencing the mechanisms that Dr. Shoenfeld had proposed for how a vaccine might set into motion a biologic process resulting in lipodystrophy. In particular, she maintained that "defects in the complement system" are understood to be an aspect of lipodystrophy's pathogenesis, and also link the condition to autoimmunity (given autoantibodies believed to be related to complement system defects associated with lipodystrophy). Mot. at 11-12. But she otherwise did not offer much in the way of explanation for how the theory she proposed was reflected in her actual experience, as set forth by the medical record.

Finally, Petitioner proposed that the timeframe in which her alleged lipodystrophy developed was medically acceptable. Noting the existence of case study reports that supported an onset of lipodystrophy within four to eight weeks of vaccination or injection (given the studies that focused on non-vaccine injections), she maintained that her "first complaint about increasing pain in her joints" represented onset of the alleged condition, and that its occurrence (at her September 14, 2012 doctor's visit) approximately seven weeks after vaccination was medically reasonable. Mot. at 13, 17.

Respondent's brief argued for the claim's dismissal. With respect to the first prong, Respondent stressed the fact that the majority of literature offered by Petitioner dealt with localized injection or vaccine responses, rather than the systemic effects complained of in this case. Opp. at 9. He also disputed how much weight could be given to the presumption that an individual suffering from one autoimmune condition (like Petitioner's thyroid problem) would necessarily experience a different one. *Id.* at 10. And Respondent challenged the scientific adequacy of Dr. Shoenfeld's theory that aluminum-based adjuvants in vaccines can initiate autoimmune reactions. *Id.* at 11.[13]

Regarding the "did cause" prong, Respondent noted that Petitioner's testing did not reveal any complement abnormalities, and thus the facts of this case were inconsistent with a large aspect of her theory. Opp. at 10. Respondent also reviewed the medical record, pointing out the lack of treater support for a lipodystrophy diagnosis as well as the lack of support for the conclusion that in fact Petitioner did suffer from this condition. *Id.* at 2-3, 6-8. And Respondent attacked the adequacy of Petitioner's *Althen* prong three showing, noting that (a) the alleged four to eight week timeframe for onset of an autoimmune condition after receipt of several vaccines relevant to

[13] Although Dr. Shoenfeld did not define in formal terms this component of his theory, in other cases it has been classified as "autoimmune syndrome induced by adjuvants," or "ASIA." Similar ASIA theories, however, have repeatedly been found to be unpersuasive by other special masters because the theory has been deemed too preliminary or unreliable given present science. *See, e.g., Rowan v. Sec'y of Health & Human Servs.*, No. 10-272V, 2014 WL 7465661 (Fed. Cl. Spec. Mstr. Dec. 8, 2014); *mot. for review den'd*, 2015 WL 3562409 (Fed. Cl. 2015); *D'Angiolini v. Sec'y of Health & Human Servs.*, No 99-578V, 2014 WL 1678145 (Fed. Cl. Spec. Mstr. Mar. 27, 2014), *mot. for review den'd*, 122 Fed. Cl. 86 (2015), *aff'd*, 645 F. App'x 1002 (Fed. Cir. 2016).

Petitioner's scientific proof, including that relating to the Tdap vaccine ,was far longer than what reliable science recognized to be reasonable, and (b) in fact the first instance in the record that could conceivably be deemed onset of anything approaching lipodystrophy was from Petitioner's October 24, 2012 visit with Dr. Honig (at which time she first expressed the view that her vaccination could have caused an injury) – 13 weeks after vaccination, and hence too long even under Petitioner's own proposed timeframe. *Id.* at 12-13.

IV. Relevant Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that she suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that her illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006). In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (*quoting Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury;

and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id*. at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs*., 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." Id. at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs*., 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases may be enough to satisfy *Althen* prong one" (emphasis in original)), *rev'd on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish her overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs*., 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not per se bind the special master to adopt the conclusions of such an individual, even if they must be

considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs*., 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dep't of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id*. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *Bazan v. Sec'y of Health & Human Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id*. at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem*., 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and

testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs*., 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd, Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs*., 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneously medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd, Murphy v. Sullivan*, 506 U.S. 974 (1992) (*citing United States v. United States Gypsum Co*., 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon

common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (*quoting Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs*., 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Human Servs*., 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (*citing Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the weighing of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of her own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the

credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.,* 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (*quoting Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (*citing Cedillo*, 617 F.3d at 1339).

Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act"). It is in the exercise of my duties as a special master to weigh competing expert testimony. *Copenhaver v. Sec'y of Health & Human Servs*., 129 Fed. Cl. 176, 183 (2016) ("Special Masters may use their discretion in weighing expert testimony, and case law supports that discretion").

In determining whether a particular expert's testimony was reliable or credible, I may consider whether the expert offers an opinion that exceeds his training or competence. *Walton v. Sec'y of Health & Human Servs*., No. 04-503V, 2007 WL 1467307, at *17-18 (Fed. Cl. Spec. Mstr. Apr. 30, 2007) (otolaryngologist not well suited to testify about disciplines other than her own specialty). While (in keeping with the liberality with which evidence offered in Vaccine Program cases is treated) I heard and have considered all of the testimony of the experts offered at the entitlement hearing, I may properly evaluate, and give appropriate weight to, whether certain testimony is beyond a particular expert's purview. *See, e.g., King v. Sec'y of Health & Human Servs*., No. 03-584V, 2010 WL 892296, at *78-79 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (petitioner's expert far less qualified to offer opinion on general causation issues pertaining to autism than specific issues pertaining to the petitioner's actual medical history, given the nature of the expert's qualifications).

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, including some articles (such as those discussing molecular mimicry and protein sequences in vaccines) that do not factor into the outcome of this decision. I have reviewed all of the medical literature submitted in this case,

but I only discuss those articles that are most relevant to my determination and/or are central to Petitioners' case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs*., No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. v. Sec'y of Health & Human Servs*., 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to — and likely undermines — the conclusion that it was not considered").

E. *Ruling on the Record*

The parties accepted my proposal to determine entitlement based on written submissions and evidentiary filings, including both side's expert reports, rather than by holding a hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *See Hooker v. Sec'y of Health & Human Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs*., 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs*., No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I am addressing the *Althen* prongs in order of their significance to my determination, rather than consistent with their sequential presentation in the Federal Circuit's decision.

A. *Althen* Prong Two

Assuming for sake of argument that Petitioner could establish that the Tdap vaccine can cause lipodystrophy, I would still be unable to conclude (based on the records filed in this case) that the vaccine likely caused *Petitioner's* lipodystrophy – because it does not appear she suffered from that condition (or any vaccine-caused injury at all). The failure to establish a claimed injury can be fatal to a petitioner's claim. *See, e.g., Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011).

First, nowhere in the record is there clear evidence that Petitioner was in fact ever diagnosed with lipodystrophy. Rather, there is evidence that Petitioner *so informed* treaters, and they dutifully wrote it down as if true, in an effort to capture accurately all facts potentially relevant to her treatment. But Program petitioners cannot establish a diagnosis simply by citing to records in which *they* informed physicians of a diagnosis that the evidence does not corroborate - any more than they can prevail in a case simply based on their own averments. *See Castaldi v. Sec'y of Health & Human Servs.*, No. 09-300V, 2014 WL 3749749, at *11 (Fed. Cl. Spec. Mstr. June 25, 2014) ("the records of treating physicians can be questioned and the weight afforded to them depends on whether the physician is noting her own observations or merely recording statements made by the patient."), *aff'd*, 119 Fed. Cl. 407 (2014).

Second, the record does not contain sufficient evidence from which it could be concluded that Petitioner more likely than not *did* have lipodystrophy, regardless of whether she was so diagnosed. Rather, the record better supports the conclusion that her longstanding medical problems, characterized by osteomalacia and/or post-gastric bypass surgery sequelae, better explain the complained-of symptoms herein. The treaters most competent to weigh in on the topic of lipodystrophy, such as Dr. Jorizzo, never made any conclusions about her complaints that could be deemed consistent with lipodystrophy in a meaningful sense.

In addition, the record also does not support the conclusion that in the months after Ms. Rothenberg's vaccination, she was experiencing *any* kind of vaccine-caused injury. No test results of any kind can be credibly pointed to in this case that would establish an undercurrent of autoimmunity of the kind often seen in other Program cases, such as inflammation. While ample medical records were filed in this case, they provide thin to no support for the conclusion that Petitioner was experiencing an autoimmune process in the many months between the July 2012 vaccination and the first time the term "lipodystrophy" appears in a medical record, or that she was undergoing some kind of underlying, at times subclinical, pathologic process.

The overall impression left by my review of the medical records filed in this case is that Petitioner is a person burdened with chronic health problems who received a vaccination, and then thereafter continued to experience such health problems – but *not* the precise injury alleged, and in fact nothing that could otherwise be persuasively deemed vaccine-related. The Tdap vaccine does not appear more likely than not to have had anything at all to do with the continuation of Petitioner's underlying problems and symptoms, and therefore Petitioner's claim lacks preponderant evidence sufficient for an entitlement award based on the "did cause" component of the *Althen* test.

B. *Althen* Prong Three

The record in this case, as interpreted by Dr. Shoenfeld's causation theory, does not support the conclusion that Petitioner's injury (assuming that it *was* lipodystrophy) occurred in a medically acceptable timeframe. I note preliminarily that it is extremely difficult even to say *when* Petitioner's lipodystrophy could be deemed to have begun. The term was not used in any records before December 2013, although Petitioner did visit treaters two months before (October 2013) complaining of skin issues that could arguably be related. Even so, the earlier October date is 15 months after vaccination – far too long to be medically acceptable, as Dr. Levinson argued, even if the few case studies that *might* connect certain vaccines to lipodystrophy are deemed persuasive.

Moreover, in the period between vaccination and October 2013, the record is replete with instances in which Petitioner sought medical treatment for a variety of medical conditions. But none of these treatment occasions have been shown to have any relationship to her later complaints that she had lipodystrophy, nor has Petitioner referenced any medical test results from the period that arguably could bulwark the timeframe as medically acceptable. Without evidence that Petitioner was experiencing symptoms over a long period of time that ultimately manifested as true lipodystrophy, I cannot conclude under such circumstances that a period in excess of a year post-vaccination is reasonable – and Dr. Shoenfeld otherwise did not persuasively establish that it would take such time for an autoimmune-caused lipodystrophy to occur.

C. *Althen* Prong One

Petitioner has not offered sufficient evidence to meet her burden of establishing a reliable theory for how a flu vaccine could cause lipodystrophy. As Dr. Levinson admitted, there is some evidence that lipodystrophy could be autoimmune in character when occurring in a localized fashion, i.e., near the place of the vaccine's administration. However, although Dr. Shoenfeld has expertise with respect to autoimmune diseases broadly, he lacks specific competence as to the alleged injury at issue to persuasively establish how *it* could be caused by vaccination. To the extent Petitioner offered reliable evidence associating *other* kinds of injections or vaccines with lipodystrophy (more often than not in the form of case studies that do not merit much weight on their face), that evidence suggests that the injury would be limited to the site of the vaccine's administration – *not* what is alleged herein. The evidence offered to support one possible mechanism, via aluminum in the vaccine used as an adjuvant, was particularly weak and reflects a causation component that has not won favor in other Program cases, as noted above.

Even if I found, however, that Petitioner *had* established sufficient reliable evidence to support this *Althen* prong, Petitioner's claim would still founder on her inability to establish (a)

that she ever experienced lipodystrophy, or (b) that in her case the Tdap vaccine caused lipodystrophy in a medically acceptable timeframe.

CONCLUSION

Petitioner has not successfully carried her burden of proof, and therefore entitlement is DENIED. Pursuant to RCFC Appendix B, the clerk of the court **SHALL ENTER JUDGMENT** in accordance with the terms of this decision.[14]

IT IS SO ORDERED.

s/ Brian H. Corcoran
Brian H. Corcoran
Special Master

[14] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.